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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/743,818	04/26/2001	Anthony Steven Weiss	GHCI1USA	8602
270	7590	11/29/2006	EXAMINER	
HOWSON AND HOWSON SUITE 210 501 OFFICE CENTER DRIVE FT WASHINGTON, PA 19034			SCHNIZER, HOLLY G	
			ART UNIT	PAPER NUMBER
			1656	

DATE MAILED: 11/29/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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# Office Action Summary

Application No.

09/743,818

Applicant(s)

WEISS, ANTHONY STEVEN

Examiner

Holly Schnizer

Art Unit

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 18 September 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 93, 112, 113 and 115-135 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 93, 112, 113 and 116-134 is/are rejected.
- 7) ☒ Claim(s) 115 and 135 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>9/18/06</u> <u>5/19/06</u> | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Status of the Claims***

Claims 93, 112-113, and new claims 115-135 are currently pending and have been considered in this Office Action.

### ***Rejections Withdrawn***

Claims 46, 48-49, 52, 54, 57, 90, and 92-114 are rejected under 35 U.S.C. 112, first paragraph, scope of enablement, in light of the amendments.

### ***Rejections Maintained***

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 93, 112-113, and 117-134 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims include regions of specific amino acid sequence that can be mutated. However, there is no support in the Specification for the particular ranges claimed.

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There is no support for making mutations specifically at one or more residues corresponding to residues specifically within positions 515-519, 515-521, 593, 595, 596, or 597 of SEQ ID NO:4. Positions 515-519 of SEQ ID NO: 4 are residues Gln Leu Arg Ala Ala, positions 515-521 of SEQ ID NO: 4 are Gln Leu Arg Ala Ala Ala Gly, residue 593 of SEQ ID NO: 4 is Val, and residue 596 of SEQ ID NO: 4 is Leu. There is no support for making mutations at these amino acids. It is noted that the sequence of SEQ ID NO:4 has the RAAAG sequence at residues 517-521. Thus, the claims are rejected.

***New Rejections Necessitated by Amendment***

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 93, 112, 113, 116, 117, 123, 125, 127, 129, 130, and 131 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 93 recites that an arginine residue corresponding to 515 of SEQ ID NO: 4 is replaced with alanine. However, SEQ ID NO:4 contains a glutamine at position 515. The claim is unclear as to what residue is to be replaced.

Claims 112 and 113 recite that an alanine at position 593 or 596 of SEQ ID NO: 4 (claim 112) or at position 593 of SEQ ID NO:4 (claim 113) is to be replaced with

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another amino acid. However, SEQ ID NO:4 contains a valine at position 593 and a leucine at position 596. The claims are unclear as to what residue is to be replaced.

Claims 117 and 131 recite making mutations in the amino acid RAAAG and RAAAGLG corresponding to positions 515-519 and 515-521 of SEQ ID NO:4, respectively. However, positions 515-521 of SEQ ID NO:4 are QLRAAAG and not the amino acids recited in the claims. Therefore, the claims are unclear as to whether positions 515-519 (QLRAA) and 515-521 (QLRAAAG) of SEQ ID NO:4 or the sequences RAAAG and RAAAGLG were intended. Clarification is required.

Claims 129 and 130 recite making mutations at position 515 of SEQ ID NO:4 wherein 515 is arginine. However, position 515 of SEQ ID NO:4 is glutamine. Thus, the claims are unclear as to what amino acid should be mutated.

Claims 116, 117, 123, 125, and 127 are unclear as to whether the tropoelastin has the amino acid sequence of SEQ ID NO:4 or 5 before the mutation (recited in claim 115) or after the mutation. Clarification is required.

### ***Claim Objections***

Claim 132 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Claim 132 recites the limitation "wherein the R in the amino acid sequence RAAAGLG is mutated". "R" is the single letter abbreviation for arginine. However, Claim 131, from which it depends, already contains the limitation "mutating the arginine of the amino acid sequence, RAAAGLG".

Claim 93 is objected to for the typographical error in misspelling of "susceptibility" in line 1 of the claim.

Claims 115, 118-127, and 135 are objected to for failing to comply with the sequence rules. The claims recite the sequence RAAAG without a sequence identifier. Where the description of a patent application discusses a sequence of 4 or more amino acids, reference must be made to the sequence by use of the sequence identifier preceded by "SEQ ID NO:" in the text of the description even if the sequence is also embedded in the text of the description of the patent application (see 37 C.F.R. 1.821, especially paragraphs (a)-(d)). Correction is required.

### ***Conclusions***

No Claims are allowable. Claims 93, 112-113, and 116-134 are rejected. Claims 115 and 135 are objected to.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the


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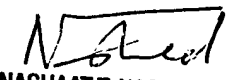
shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Holly Schnizer whose telephone number is (571) 272-0958. The examiner can normally be reached on Tuesday-Thursday from 10 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached on (571) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

  
Holly Schnizer  
November 24, 2006

  
NASHAAT T. NASHED PHD.  
PRIMARY EXAMINER